REMARKS

Claims 1-7 are pending in the application. Claims 1-4, 6 and 7 are rejected. Claim 5 is objected to but would be allowable if placed in independent form. New claim 8 is added. Support for this claim is based on the description of the catheter as a "unit" throughout the specification and the illustrations in the drawings.

Claim Rejections - 35 U.S.C. § 103

Claims 1 and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tsukada et al (6,695,831) in view of Cohen et al (6,162,201). This rejection is traversed for at least the following reasons.

The invention is directed to an intermittent urethra self-retaining catheter set comprising (1) a catheter unit and (2) a disinfectant casing with cap. Notably, with reference to the non-limiting but exemplary embodiment in Figs. 1 and 2, the catheter unit 1 includes a catheter body 11 having a urine-guiding passage 111 and a water-guiding passage 112 that extend within the body in a longitudinal direction. A balloon 12 is attached to a distal end of the catheter body 11 and communicates via the water-guiding passage 112 in a branched tube 14 bifurcated from the catheter body 11 with a reservoir 16. An on-off valve 17 is attached to an intermediate portion of the branched tube 14. A reinforcement tube 18 is inserted into an upper interior of the urine guiding passage 111 in the catheter body 11. The on-off valve is adapted to open and close a passage in which sterilized water flows between the reservoir 16 and the balloon 12 on the catheter body.

As is clear from the Figures, the catheter body 11 is (1) a unitary construction and (2) sized to support the reservoir and the balloon, so that (3) it is useable by an individual alone, as explained at page 3 of the original specification.

Claim 1

Claim 1 is substantially directed to the combination of catheter unit, disinfectant casing and cap. The dependent claims 2-7 specify additional features of the branched tube 14 (claim 2), cap (claim 3), on-off valve (claim 5), and additional features such as a magnet (claim 4), absorbing material (claim 6) and body shape (claim 7).

Tsukada '831

The Examiner points to Tsukada in Fig. 1 for disclosure of a catheter unit 1, disinfectant casing 2 and cap 41. The Examiner notes the existence of a reinforcement tube 101, as illustrated in Fig. 4. The Examiner admits that Tsukada '831 does not disclose a water-guiding passage, a balloon attached to a distal end of the catheter, a branched tube bifurcated from the catheter, a reservoir attached to a free end of the branched tube and an on-off valve attached to the branched tube. Each of these structural features of the catheter body are critical additions to the early products and designs developed by the Inventor Tsukada, as represented by Tsukada '831.

Cohen et al

The Examiner looks to Cohen for teaching of the use in a unitary catheter of a water-guiding passage 42, balloon 24, branched tube B, reservoir (col. 4, lines 20-21) and on-off valve (col. 2, lines 4-6).

However, upon careful consideration of Cohen, particularly the illustrations in Figs. 1 and 2, it is clear that there are two parts to the structure, each having a separate body.

The first part illustrated in Fig. 1 includes the catheter 10 with body 12 having an entrance 16 and a pair of retention balloons 24, 26. The structure includes a fluid passage 28 and, at an outlet end 20, a valve 22. The distinct structures that form the catheter 10 are described at col. 3, line 35 - col. 4, line 13. Contrary to the Examiner's assertion, the channel 42 is not in the body of catheter 10.

The second part is illustrated in Fig. 2 and is directed to an insert/removal member 30, having at a coupling end 38 a sleeve 40 that engages the outlet 18 of the catheter 10. The member has a channel 42 for carrying water and a portion that branches from a handle to an inlet port 44. The handle does not have any fluid passage. The distinct structures that form insertion/removal member 30 are described at col. 4, line 14 - 39. In use, the combination of the catheter 10 and insertion/removal member 30 is explained at col. 8, line 50 - col. 9, line 27.

One Part vs Two Part Structure

Clearly, this two-part structure of Cohen et al differs from the one-part structure of the present invention, which combines the balloon and reservoir and branching unit on a single integral catheter body.

Different Branching Structure

Moreover, the branching for the sterilized water is taken from a main structure axially aligned and adapted to contain the cap and urine outlet.

Different Operation

Clearly, the one-part structure in the present invention also operates differently from that of Cohen et al, where the water from the inlet port 42 via the insert/removal member 30 is provided to fill the retention balloons 24, 26 and, following closure of the valve 22, permits withdrawal of the member 30. The two-part structure in Cohen is neither as compact nor easy to use as the present invention, especially by an individual alone.

Because of these several differences, the combination of Tsukada '831 and Cohen would not lead to the present invention. Indeed, the Examiner even admits that Tsukada '831 combined with Cohen does not expressly point out the attachment of a valve to the branched tube.

The Examiner asserts, however, that it would be obvious to one having skill in the art to attach the valve to the branch tube because the relocation of the valve of Cohen from one liquid passed to the other is a matter of optimization. Applicants respectfully submit that this is more than optimization, it is a practical effect that is not present in the Cohen structure. As already noted, in Cohen, the valve cannot be moved from the branch passage since it must be present in the linear portion of the catheter to prevent the escape of water from the balloons once they have been inflated and once the insert/removal member 30 has been removed.

Claims 2-7

Given the patentability of claim 1, the remaining dependent claims should be patentable. Therefore, it is unnecessary to separately distinguish the features from those of the present invention.

New Claim

Applicants have added new claim 8, which states that the catheter body is a "unitary structure."

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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